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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,449

12/30/2003

Richard D. Keeven

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28078 7590 06/09/2009

MAGINOT, MOORE & BECK, LLP

CHASE TOWER

111 MONUMENT CIRCLE

SUITE 3250

INDIANAPOLIS, IN 46204

EXAMINER

WOODALL, NICHOLAS W

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

06/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/748,449	<b>Applicant(s)</b> KEEVEN ET AL.	
	<b>Examiner</b> Nicholas Woodall	<b>Art Unit</b> 3775	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-36 is/are pending in the application.
- 4a) Of the above claim(s) 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This action is in response to applicant's amendment received on 03/09/2009.

#### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the femoral resection guide when mated with the connector member is further away from the tibia when the augment is fixed to the positioning member than when the augment is not fixed to the positioning member must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

Art Unit: 3775

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 24-27, 33, and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 24 lines 9-13 contains limitations that the examiner does not believe to be shown in the drawings or provided in the specification and are being treated as new matter (see the drawing objection above for more details).

***Claim Rejections - 35 USC § 101***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24-36 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 24, lines 3-4, the applicant positively recites part of a human, i.e. "...that defines a femur facing side and a tibia facing side...". In claim 28, line 4, the applicant positively recites part of a human, i.e. "...defining a femur facing

Art Unit: 3775

side, a tibia facing side...”. Thus claims 24-36 include a human within their scope and are non-statutory. The examiner believes claims 24 and 28 should state something along the lines ...that defines a side configured to face a femur and a side configured to face a tibia... and will be interpreted as such for examination purposes.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 24, 33, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Dietz (U.S. patent 5,653,714).

Dietz discloses a device comprising an instrument, an augment, and a resection guide (40) capable of being used on a femur or a tibia. The instrument includes a positioning member (10) that defines a side surface capable of facing a femur, a generally planar side surface capable of facing a tibia, a first coupler (24), and a connector member including a first mating feature (recess in element 34; see column 2 lines 54-56). The augment includes an upper surface, a contoured lower surface, and a second coupler (16) that cooperates with the first coupler to fix the augment to the

Art Unit: 3775

positioning member, wherein the upper surface of the augment abuts the side surface capable of facing a tibia when the augment is fixed to the positioning member. The resection guide includes a second mating feature (36) that mates with the first mating feature of the instrument, wherein the device is configured such that when the resection guide is mated to the connector member and the device is on a tibia, the resection guide is positioned farther away from the tibia when the augment is fixed to the positioning member than when the augment is not fixed to the positioning member.

8. Claims 28, 31, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Buechel (U.S. Patent 4,738,254).

Buechel discloses a device comprising an instrument, an augment, and an intramedullary pin (14). The instrument includes a positioning member including a first coupler/bore (52) and a handle (29/30) extending from the positioning member and defining a side configured to face a femur, a side configured to face a tibia, and a guide slot (39) that receives the intramedullary pin. The augment includes a second coupler/pin (76) that is received within the first coupler to fix the augment to the positioning member.

9. Claims 28, 35, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Androphy (U.S. Patent 4,487,203).

Androphy discloses a device (for example Figure 7) comprising an instrument, an augment (38), and an intramedullary pin (34). The instrument includes a positioning member (108) including a first coupler (110) and defining a side configured to face a femur, a planar side configured to face a tibia, and a guide slot (118) that receives the

Art Unit: 3775

intramedullary pin. The guide slot extends from the femur facing side to the tibia facing side and opens to a front portion of the positioning member. The augment includes an upper surface, a lower surface, an augment slot (56) extending from the upper surface to the lower surface and opens to a front portion of the augment, and a second coupler (60) that cooperates with the first coupler to fix the augment to the positioning member, wherein the augment slot is positioned and aligned with the guide slot such that when the augment is fixed to the positioning member the upper surface of the augment (the surface element 110 projects from) abuts the tibia facing side of the positioning member (the surface that element 110 is inserted into element 60).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dietz (U.S. patent 5,653,714).

Dietz discloses the invention as claimed except for the first coupler including a bore and the second coupler including a pin that is received within the bore. Dietz discloses a device comprising a first coupler of a positioning member including a pin/tongue, i.e. a slender, usually cylindrical, piece of wood or metal for holding or fastening parts together, and a second coupler of an augment including a bore/groove that receives the pin. It would have been obvious to one having ordinary skill in the art

at the time the invention was made to provide the device of Dietz wherein the first coupler includes a bore and the second coupler includes a pin, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

12. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Androphy (U.S. Patent 4,487,203).

Androphy discloses the invention as claimed except for the first coupler including a bore and the second coupler including a pin that is received within the bore. Androphy discloses a device comprising a first coupler of a positioning member including a pin, i.e. a slender, usually cylindrical, piece of wood or metal for holding or fastening parts together, and a second coupler of an augment including a bore that receives the pin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Androphy wherein the first coupler includes a bore and the second coupler includes a pin, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

### ***Response to Arguments***

13. Applicant's arguments, see the applicant's arguments, filed 03/09/2009, with respect to the rejection(s) of claim(s) 28 under 35 U.S.C. 102(b) in view of LaSalle have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of



Buechel and Androphy as discussed above. The examiner has provided new grounds of rejections not necessitated by the amendment making this office action non-final.

### ***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/748,449  
Art Unit: 3775

Page 9

/Nicholas Woodall/  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
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Unit 3775